

REMARKS

This amendment is responsive to the May 18, 2006 Office Action. In the Office Action, Examiner Eric S. DeJong:

- objected to page 10, lines 2 and 3, of the specification because of a hyperlink;
- rejected claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite on the basis of three separate phrases; and
- rejected claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory algorithm type subject matter.

With this amendment, Applicants' specification has been amended to remove a URL to a reference in favor of a citation for the reference. In addition, claims 14, 17, 20, 22, 39, 42, 45-47, and 58 have been amended for clarity. Specifically, independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 have been amended to recite "the correlation values of all genotypic data structures." Support for this amendment is found on page 5, lines 5-8, of Applicants' specification. Claims 15, 21, and 40 each ultimately depends upon claims 14, 19, and 39, respectively. Accordingly, no new matter has been added by virtue of these claim amendments or the amendments to the specification. Upon entry of the present amendments, claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 will remain pending in the above-identified application. Entry of the present amendments to the claims, drawings, and specification is respectfully requested.

THE OBJECTION TO THE SPECIFICATION SHOULD BE WITHDRAWN

In the May 18, 2006 Office Action, the Examiner objected to an embedded hyperlink that appears on page 10 of the specification. In response, Applicants have removed the hyperlink and amended a reference citation to refer to a published research article that used to be "*in press*" when the instant application was originally filed. No new matter has been added by these amendments. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

**THE 35. U.S.C. § 112, SECOND PARAGRAPH, REJECTION SHOULD BE
WITHDRAWN**

The Examiner has rejected claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicants respectfully traverse the rejections for the reasons discussed below.

First 35 U.S.C. § 112, second paragraph, rejection. Firstly, the Examiner has rejected independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, because the phrase “said **one or more** genotypic data structures that are not in said one or more genotypic data structures” allegedly lacks sufficient antecedent basis as the claims do not recite any limitation or step drawn to identifying or determining a set of genotypic data structures that **are not** in the group of genotypic data structures.¹ In response, Applicants note that the identifying step in claim 14, as amended, provides a method for identifying one or more genotypic data structures within a plurality of genotypic data structures. Thus, the plurality of genotypic data structures are divided into two subsets: one or more genotypic data structures, *i.e.*, the group of genotypic data structures in the Examiner’s comment, (“**first subset**”) and the genotypic data structures that are NOT in one or more genotypic data structures (“**second subset**”). Because the **first subset** and the **second subset** must be mutually exclusive by their very nature, identifying one subset sufficiently identifies the other subset. The identifying step recited in claim 14 particular points out and distinctly claims the **first subset**. Therefore, the **second subset** is also defined. Specifically, claim 14, as amended, provides:

identifying one or more genotypic data structures in said plurality of genotypic data structures, wherein the correlation value for each respective genotypic data structure in the one or more genotypic data structures is a high correlation value relative to the correlation values of all genotypic data structures in said plurality of genotypic data structures that are not in said one or more genotypic data structures

In the determining step that precedes the identifying step in claim 14, each genotypic data structure in the plurality of genotypic data structures is compared with a phenotypic data structure to define a correlation value. Multiple correlation values may be computed when

¹ Applicants respectfully note that the phrase actually reads genotypic data structures “in said **plurality** of genotypic data structures that are not in said one or more genotypic data structures.”

the same genotypic data structure is compared with different phenotypic data structures. As set forth in the identifying step of claim 14 as amended, for a given phenotypic data structure, a correlation value associated with each respective genotypic data structure in the **first subset** is higher than any correlation value associated with any genotypic data structure in the **second subset**.

The specification provides examples of the identifying step recited in claim 14. For example, one method for identifying the **first subset** (and therefore the **second subset**) is set forth in step 214 of Applicants' FIG. 2 as well as page 27, lines 26-31 of Applicants' specification. Each genotypic data structure has a correlation value that defines its correlation to a phenotypic data structure. Therefore, in accordance with the identifying step of claim 14, it is possible to rank all genotypic data structures in the plurality of genotypic data structures, which encompass both the **first subset** and the **second subset**, using the correlation values to a given phenotypic data structure, as taught on page 27, lines 26-31, of the instant specification. Once the ranking process is finished, the **first subset** is defined as the genotypic data structures that are ranked in the top and the **second subset** is defined as the genotypic data structure that are not ranked in the top. In one embodiment, a cutoff value, shown as 402 in Applicants' Figures 4A-4D and described on page 31, lines 22-23 of the specification, separates the **first subset** and the **second subset**. Accordingly, as recited in claim 14 as amended, any correlation value of the genotypic data structures in the **first subset** will be higher than any correlation value of the genotypic data structures in the **second subset**.

The Examiner further reasons that the claims do not recite any limitation or step drawn to identifying or determining a set of genotypic data structures that **are not** in the group of genotypic data structures resulting from the previously recited steps of 'repeating said establishing and determining steps' in the instant claims. Applicants respectfully point out that such a limitation or step is not necessary. Specifically, claim 14 recites:

repeating said establishing and determining steps for each locus in said plurality of loci, thereby establishing a plurality of genotypic data structures and, for each respective genotypic data structure in the plurality of genotypic data structures, determining a correlation value

Repeating the establishing and determining steps, as defined above, establishes "a plurality of genotypic data structure," *i.e.* "the group of genotypic data structures" in the Examiner's comments as well as correlation values for each of these genotypic data structures. Because

the **second subset** is a subset of the plurality of genotypic data structures, each genotypic data structure within the **second subset** has a correlation value. Thus, the genotypic data structures in the plurality of genotypic data structures that are not in the one or more genotypic data structures already have correlation values and do not require additional limitations or steps.

Claims 15, 17, 20-22, 39, 40, 42, 45-47, and 58 in their present form either recite or depend from a claim which determines correlation values in the same way as claim 14, as amended, and are therefore patentable for at least the same reasons that claim 14.

Second 35 U.S.C. § 112, second paragraph, rejection. The Examiner has rejected independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis for the recitation of the phrase: “the correlation value for each respective genotypic data structure in the one or more genotypic data structures is a high correlation value relative to the correlation values of genotypic data structures that are not in said one or more genotypic data structures.”² The Examiner contends that “the use of the relative term ‘high correlation value’ is indefinite as neither the instant claims nor the instant specification provide a requisite threshold for when a given correlation value is to be considered a ‘high correlation value.’” Applicants disagree.

Applicants respectfully point out that a specific “high correlation value” cannot be provided because appropriate choices for the high correlation value may vary considerably based on choice of phenotype, loci and organism. The specification provides ample teaching for selecting an appropriate high correlation value. For example, page 28, lines 8 to 11, of Applicants’ specification states:

In processing step 216, the genotypic data structures that achieve the highest correlation values are selected. Since each genotypic data structure corresponds to a particular locus in the genome, the selection process in processing step 216 results in the association of the phenotype with particular loci in the organism of interest.

² Applicants respectfully note that the phrase actually reads “the correlation value for each respective genotypic data structure in the one or more genotypic data structures is a high correlation value relative to the correlation values of genotypic data structures **in said plurality of genotypic data structures** that are not in said one or more genotypic data structures.”

Also, page 28, lines 11 to 14, of the specification states that genotypic data structures that form a correlation value that is a predetermined number of standard deviations above the mean correlation value are selected. Page 28, lines 15 to 17, of Applicants' specification explains that, in one embodiment, the predetermined number is chosen so that a small percentage of the genome of the organism, such as five percent, will be selected. Additional examples of the choices for the high correlation values provided in Applicants' specification include "a genome-wide threshold of ten percent" and a percentage that ranges "from two percent to nineteen percent of the complete mouse genome." See page 34, line 16 and lines 5-6, respectively, of Applicants' specification. Column 5 of Table 3 on page 33 of Applicants' specification clearly illustrates that the threshold needed (*i.e.*, the choice of a high correlation value) to arrive at a **first subset** of genotypic data structures that is a small percentage of the genome of the organism varies with respect to a specific phenotype that is being analyzed (*e.g.*, threshold values of 19, 17, 8, 4, and 2 percent). Further examples of suitable choices for high correlation values are found in Figures 7 through 12 of Applicants' specification. For example, Figure 7 demonstrates that a cutoff value may be chosen to select, for example, a cutoff value of 5%. A toggle function, as depicted in Figure 7, allows the cutoff value (*i.e.*, the choice for high correlation value) to be adjusted according to the type and size of the genotypic data structures. The cited examples clearly demonstrate that the proper choice for "a high correlation value" differs on a case by case basis. As such, an arbitrary number such as five percent cannot be assigned to "small percent of the genome." Because each "small percent of the genome" corresponds to a high correlation value, such a high correlation value also varies with respect to different types and sizes of genotypic data structures and therefore, assignment of a predetermined number for the high correlation value recited in the rejected claims is inappropriate and unnecessary.

Based on preceding analysis and examples, Applicants respectfully submit that the phrase "high correlation value" provides a suitable and concrete definition of the metes and bounds of the rejected claims. As such, Applicants believe that claims 14, 17, 20, 22, 39, 42, 45-47, and 58 are patentable.

Third 35 U.S.C. § 112, second paragraph, rejection. The Examiner has rejected independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 under 35 U.S.C. § 112, second paragraph, for reciting the phrase "an amount of said genome is included in each locus in said plurality of loci is predetermined" or depending on a claim that recites this phrase.

Applicants have amended the phrase to recite “an amount of said genome that is included in each locus in said plurality of loci is predetermined at a time prior to said identifying step.” As such, a clear limitation is set forth for when an amount of said genome that is included in each locus in said plurality of loci is predetermined. Accordingly, Applicants respectfully believe that the 35 U.S.C. § 112, second paragraph, rejection of independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 is moot based on these amendments. The instant specification recites an example of an embodiment of “an amount of said genome” on page 15, lines 19-33:

In some embodiments of the present invention, the size of the locus L that is selected in each instance of processing step 204 may be set to a specific size. For example, when the genotypic database 52 is a SNP database, the size of locus L is set to a predetermined number of centiMorgans (cM). Then, in each instance of processing step 204, a different locus having the predetermined number of cM is chosen... One cM is equal to a one percent chance that a marker at one genetic position will be separated from a marker at another position due to crossing over in a single generation... In some embodiments, the size of the locus L selected in processing step 204 is less than 5 cM, 10 cM, 20 cM, 30 cM, 50 cM, 100 cM or a value greater than 100 cM.

Clearly, the size of the amount of said genome is determined at a time prior to the identification of the one or more genotypic data structures. In the example above, an amount of genome that is included in each locus is measured in centiMorgans. The paragraph beginning on page 15, line 34, of Applicants’ specification further recites:

It will be appreciated that units other than cM may be used to set the size of the locus L selected in each instance of processing step 204. For example, the size of the locus L may be set in units of nucleotides or even kilobases of nucleotides. In one embodiment, once the size of the locus has been initially set in a given session, each different locus L that is selected in subsequent instances of processing step 204 is chosen such that it has the same size as the locus L that was initially selected.

Thus, Applicants’ specification provides explicit definition that defines “an amount of said genome” and that an amount of the genome that is included in each locus is predetermined prior to identifying genotypic data structures.

In light of the claim amendments and these comments, Applicants respectfully request that the 35 U.S.C. § 112, second paragraph, rejection of claims 14, 17, 20, 22, 39, 42, 45-47, and 58 be withdrawn.

THE 35. U.S.C. § 101 REJECTION SHOULD BE WITHDRAWN

The Examiner has rejected independent claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 under 35. U.S.C. § 101 because the claims are allegedly directed to non-statutory subject matter. Applicants have amended 14, 17, 20, 22, 39, 42, 45-47, and 58 such that a communicating step is added. For example, in the amended claim 14, the communicating step recites “communicating said one or more genotypic data structures.” As such, amended claim 14 not only includes steps for establishing and analyzing genotypic data structures (*e.g.*, determining and calculating steps are performed), it also requires that a result be communicated (*e.g.*, to a practitioner). In claim 14, the result is one or more genotypic data structures that are identified in the identifying step. As such, claim 14 explicitly includes a tangible result. The same amendment has been made to remaining rejected independent claims 17, 20, 22, 39, 42, 45-47, and 58. Claims 15, 21, and 40 each ultimately depends upon claims 14, 20, and 39, respectively.

In light of the claim amendments and the above comments, Applicants respectfully request that the 35 U.S.C. § 101 rejection of claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the subject application is in good and proper order for allowance. Withdrawal of the Examiner's rejections and objections and early notification to this effect are earnestly solicited.

No fee is believed owed in connection with filing of this amendment and response. However, should the Commissioner determine otherwise, the Commissioner is authorized to charge any underpayment or credit any overpayment to Jones Day Deposit Account No. 50-3013 for the appropriate amount. A copy of this sheet is attached.

Respectfully submitted,

Date: November 16, 2006


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Amendments to the Drawings:

The attached sheets of drawings include an amendment to Figure 10. A new reference number “1002” for an element that was previously labeled as 1006 is added in red ink in Figure 10. The element has been described in the original specification, thus does not add new matter to the instant application.

Attachments: **Appendix A** Replacement Sheet for Figure 10

Appendix B Annotated Sheet Showing Changes to Figure 10

